

AMENDMENTS TO THE CLAIMS

Please cancel Claims 1-20, without prejudice (Claims 21-45 having been previously cancelled), and add new Claims 46-85.

Claims 1-45 (Canceled).

--46.(New) A method of treating small intestinal bacterial overgrowth (SIBO) or SIBO-caused irritable bowel syndrome in a human subject, said method comprising:

detecting in the subject by suitable detection means, the presence or absence of SIBO, and, if the presence of SIBO is detected, wherein a population of bacteria is present in the small intestine of the subject,

depriving the population of nutrients sufficiently to at least partially eradicate SIBO in the subject.

47.(New) The method of Claim 46, wherein depriving the population of nutrients further comprises:

causing the subject to consume, for a sustained period, a diet consisting essentially of nutrients that upon arrival in the upper gastrointestinal tract of the subject, are at least partially predigested, said sustained period being sufficient to at least partially eradicate SIBO in the human subject.

48.(New) The method of Claim 47, wherein the period is at least about three days.

49.(New) The method of Claim 47, wherein the at least partially predigested nutrients are contained in a commestible total enteral nutrition formulation.

50.(New) The method of Claim 47, further comprising:

administering to the subject a pancreatic enzyme supplement before or substantially simultaneously with a meal, such that nutrients contained in said meal are

at least partially predigested in the upper gastrointestinal tract of the subject by the activity of said pancreatic enzyme supplement.

51.(New) The method of Claim 46, wherein depriving the population of nutrients further comprises:

enhancing the digestion and/or absorption of the nutrients in the upper gastrointestinal tract of the subject by slowing transit of said nutrients across the upper gastrointestinal tract of said human subject, thereby at least partially depriving the bacterial population of the nutrients.

52.(New) The method of Claim 51, wherein enhancing the digestion and/or absorption of the nutrients in the upper gastrointestinal tract further comprises:

administering a pharmaceutically acceptable composition to said subject by an oral or enteral delivery route, said human subject having an intrinsic cholinergic afferent neural pathway projecting from a peptide YY-sensitive primary sensory neuron in the intestinal wall of said subject to a prevertebral celiac ganglion and having an adrenergic efferent neural pathway projecting from said ganglion to one or more enterochromaffin cells in the intestinal mucosa and/or to a serotonergic interneuron linked in a myenteric plexus and/or submucous plexus to an opioid interneuron, said opioid interneuron also being linked by an intestino-fugal opioid pathway projecting to said ganglion, with one or more neural connections to the central nervous system and back to the gut projecting from the ganglion,

said pharmaceutically acceptable composition comprising an active agent, said active agent being selected from the group consisting of

- (A) active lipids;
- (B) serotonin, serotonin agonists, or serotonin re-uptake inhibitors;
- (C) peptide YY or peptide YY functional analogs;
- (D) calcitonin gene-related peptide or functional analogs thereof;
- (E) adrenergic agonist;
- (F) opioid agonists;

(G) combinations of any of (A), (B), (C), (D), (E) and/or (F); and

(H) antagonists of receptors for any of (B), (C), (D), (E) and/or (F),

said active agent being delivered in an amount and under conditions such that the cholinergic intestino-fugal pathway, at least one prevertebral ganglionic pathway, the adrenergic efferent neural pathway, the serotonergic interneuron and/or the opioid interneuron are activated by the action of any of (A) through (G), whereby the rate of upper gastrointestinal transit in the subject is slowed, thereby enhancing the digestion and/or absorption of the nutrients in the upper gastrointestinal tract of said human subject.

53.(New) The method of Claim 51, wherein enhancing the digestion and/or absorption of the nutrients in the upper gastrointestinal tract further comprises:

administering a gastrointestinal transit-slowng composition comprising a carrier and a dispersion consisting essentially of an active lipid in the carrier, the active lipid being selected from the group consisting of saturated and unsaturated fatty acids, fully hydrolyzed fats and mixtures thereof, in an amount and in a form effective to promote contact of the lipid with the subject's small intestine and thereby slow gastrointestinal transit and at least partially eradicate SIBO in the human subject.

54.(New) The method of Claim 53, wherein the active lipid is selected from the group consisting of:

(A) caprolic acid, caprylic acid, capric acid, lauric acid, myristic acid, oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acid, linolenic acid, trans-hexadecanoic acid, elaidic acid, columbinic acid, arachidic acid, behenic acid, eicosenoic acid, erucic acid, brassidic acid, cetoleic acid, nervonic acid, Mead acid, arachidonic acid, timnodonic acid, clupanodonic acid, or docosaheptaenoic acid;

(B) pharmaceutically acceptable salts of any of (A); and

(C) mixtures of any of (A) or (B).

55.(New) The method of Claim 54, wherein the active lipid comprises oleic acid or a pharmaceutically acceptable oleate salt.

56.(New) The method of Claim 53, wherein the active lipid comprises fully hydrolyzed fats.

57.(New) The method of Claim 53, wherein the active lipid comprises a fatty acid or a pharmaceutically acceptable salt thereof.

58.(New) The method of Claim 53, wherein the active lipid is:

(A) a fatty acid selected from the group of (C4-C24) saturated and unsaturated fatty acids;

(B) a pharmaceutically acceptable salt of any of (A); or

(C) a mixture of any of (A) and/or (B).

59.(New) The method of Claim 53, wherein the fatty acid comprises oleic acid, a pharmaceutically acceptable oleate salt, or a mixture of either of these with other fatty acids or salts thereof.

60.(New) The method of Claim 52, wherein oral administration is by ingestion of coated or uncoated microspheres or particles, of a dispersible powder or granule formulation, of a suspension, emulsion, solution, syrup, or elixir, or of a coated or uncoated tablet, troche, capsule, caplet, or lozenge.

61.(New) The method of Claim 53, wherein oral administration is by ingestion of coated or uncoated microspheres or particles, of a dispersible powder or granule formulation, of a suspension, emulsion, solution, syrup, or elixir, or of a coated or uncoated tablet, troche, capsule, caplet, or lozenge.

62.(New) The method of Claim 52, wherein the active agent is selected from the group consisting of serotonin, serotonin agonists, serotonin re-uptake inhibitors, 5-HT3 receptor antagonists, and 5-HT4 receptor antagonists.

63.(New) The method of Claim 62, wherein the active agent is serotonin, and the serotonin is administered to the human subject, before or substantially simultaneously with a meal, in an amount from about 0.03 to about 0.1 mg/kg body mass.

64.(New) A method of treating small intestinal bacterial overgrowth (SIBO) or SIBO-caused irritable bowel syndrome in a human subject, said method comprising:

detecting in the subject by suitable detection means, the presence or absence of SIBO, and, if the presence of SIBO is detected, wherein a population of bacteria is present in the small intestine of the subject,

causing the subject in whom the presence of SIBO is detected to consume, for a sustained period, a comestible total enteral nutrition formulation, so that the population is deprived of nutrients sufficiently to at least partially eradicate SIBO in the subject.

65.(New) The method of Claim 64, wherein the period is at least about three days.

66.(New) A method of treating small intestinal bacterial overgrowth (SIBO) or a SIBO-associated condition in a human subject, said condition being selected from the group consisting of impaired mentation and impaired memory, said method comprising:

detecting in the subject by suitable detection means, the presence or absence of SIBO, and, if the presence of SIBO is detected, wherein a population of bacteria is present in the small intestine of the subject,

depriving the population of nutrients sufficiently to at least partially eradicate SIBO in the subject.

67.(New) The method of Claim 66, wherein depriving the population of nutrients further comprises:

causing the subject to consume, for a sustained period, a diet consisting essentially of nutrients that upon arrival in the upper gastrointestinal tract of the subject, are at least partially predigested, said sustained period being sufficient to at least partially eradicate SIBO in the human subject.

68.(New) The method of Claim 67, wherein the period is at least about three days.

69.(New) The method of Claim 67, wherein the at least partially predigested nutrients are contained in a commestible total enteral nutrition formulation.

70.(New) The method of Claim 67, further comprising:

administering to the subject a pancreatic enzyme supplement before or substantially simultaneously with a meal, such that nutrients contained in said meal are at least partially predigested in the upper gastrointestinal tract of the subject by the activity of said pancreatic enzyme supplement.

71.(New) The method of Claim 66, wherein depriving the population of nutrients further comprises:

enhancing the digestion and/or absorption of the nutrients in the upper gastrointestinal tract of the subject by slowing transit of said nutrients across the upper gastrointestinal tract of said human subject, thereby at least partially depriving the bacterial population of the nutrients.

72.(New) The method of Claim 71, wherein enhancing the digestion and/or absorption of the nutrients in the upper gastrointestinal tract further comprises:

administering a pharmaceutically acceptable composition to said subject by an oral or enteral delivery route, said human subject having an intrinsic cholinergic afferent neural pathway projecting from a peptide YY-sensitive primary sensory neuron

in the intestinal wall of said subject to a prevertebral celiac ganglion and having an adrenergic efferent neural pathway projecting from said ganglion to one or more enterochromaffin cells in the intestinal mucosa and/or to a serotonergic interneuron linked in a myenteric plexus and/or submucous plexus to an opioid interneuron, said opioid interneuron also being linked by an intestino-fugal opioid pathway projecting to said ganglion, with one or more neural connections to the central nervous system and back to the gut projecting from the ganglion,

said pharmaceutically acceptable composition comprising an active agent, said active agent being selected from the group consisting of

- (A) active lipids;
- (B) serotonin, serotonin agonists, or serotonin re-uptake inhibitors;
- (C) peptide YY or peptide YY functional analogs;
- (D) calcitonin gene-related peptide or functional analogs thereof;
- (E) adrenergic agonist;
- (F) opioid agonists;
- (G) combinations of any of (A), (B), (C), (D), (E) and/or (F); and
- (H) antagonists of receptors for any of (B), (C), (D), (E) and/or (F),

said active agent being delivered in an amount and under conditions such that the cholinergic intestino-fugal pathway, at least one prevertebral ganglionic pathway, the adrenergic efferent neural pathway, the serotonergic interneuron and/or the opioid interneuron are activated by the action of any of (A) through (G), whereby the rate of upper gastrointestinal transit in the subject is slowed, thereby enhancing the digestion and/or absorption of the nutrients in the upper gastrointestinal tract of said human subject.

73.(New) The method of Claim 71, wherein enhancing the digestion and/or absorption of the nutrients in the upper gastrointestinal tract further comprises:

administering a gastrointestinal transit-slowng composition comprising a carrier and a dispersion consisting essentially of an active lipid in the carrier, the active lipid being selected from the group consisting of saturated and unsaturated fatty

acids, fully hydrolyzed fats and mixtures thereof, in an amount and in a form effective to promote contact of the lipid with the subject's small intestine and thereby slow gastrointestinal transit and at least partially eradicate SIBO in the human subject.

74.(New) The method of Claim 73, wherein the active lipid is selected from the group consisting of:

(A) caprolic acid, caprylic acid, capric acid, lauric acid, myristic acid, oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acid, linolenic acid, trans-hexadecanoic acid, elaidic acid, columbinic acid, arachidic acid, behenic acid, eicosenoic acid, erucic acid, bressidic acid, cetoleic acid, nervonic acid, Mead acid, arachidonic acid, timnodonic acid, clupanodonic acid, or docosahexaenoic acid;

(B) pharmaceutically acceptable salts of any of (A); and

(C) mixtures of any of (A) or (B).

75.(New) The method of Claim 74, wherein the active lipid comprises oleic acid or a pharmaceutically acceptable oleate salt.

76.(New) The method of Claim 73, wherein the active lipid comprises fully hydrolyzed fats.

77.(New) The method of Claim 73, wherein the active lipid comprises a fatty acid or a pharmaceutically acceptable salt thereof.

78.(New) The method of Claim 73, wherein the active lipid is:

(A) a fatty acid selected from the group of (C4-C24) saturated and unsaturated fatty acids;

(B) a pharmaceutically acceptable salt of any of (A); or

(C) a mixture of any of (A) and/or (B).

79.(New) The method of Claim 73, wherein the fatty acid comprises oleic acid, a pharmaceutically acceptable oleate salt, or a mixture of either of these with other fatty acids or salts thereof.

80.(New) The method of Claim 72, wherein oral administration is by ingestion of coated or uncoated microspheres or particles, of a dispersible powder or granule formulation, of a suspension, emulsion, solution, syrup, or elixir, or of a coated or uncoated tablet, troche, capsule, caplet, or lozenge.

81.(New) The method of Claim 73, wherein oral administration is by ingestion of coated or uncoated microspheres or particles, of a dispersible powder or granule formulation, of a suspension, emulsion, solution, syrup, or elixir, or of a coated or uncoated tablet, troche, capsule, caplet, or lozenge.

82.(New) The method of Claim 72, wherein the active agent is selected from the group consisting of serotonin, serotonin agonists, serotonin re-uptake inhibitors, 5-HT₃ receptor antagonists, and 5-HT₄ receptor antagonists.

83.(New) The method of Claim 82, wherein the active agent is serotonin, and the serotonin is administered to the human subject, before or substantially simultaneously with a meal, in an amount from about 0.03 to about 0.1 mg/kg body mass.

84.(New) A method of treating small intestinal bacterial overgrowth (SIBO) or SIBO-caused irritable bowel syndrome in a human subject, said method comprising:

detecting in the subject by suitable detection means, the presence or absence of SIBO, and, if the presence of SIBO is detected, wherein a population of bacteria is present in the small intestine of the subject,

causing the subject in whom the presence of SIBO is detected to consume, for a sustained period, a comestible total enteral nutrition formulation, so that

the population is deprived of nutrients sufficiently to at least partially eradicate SIBO in the subject.

85.(New) The method of Claim 84, wherein the period is at least about three days.

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